

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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MICHAEL CHIARACANE AND LUIS :  
MALDONADO,

Plaintiffs,

v.

PORT AUTHORITY TRANS-HUDSON :  
CORPORATION,

Defendant. :

-----X

KEVIN NATHANIEL FOX  
UNITED STATES MAGISTRATE JUDGE

**MEMORANDUM AND ORDER**

18-CV-2995 (KNF)

This is an action for damages pursuant to the Federal Employers' Liability Act ("FELA"), 45 U.S.C. § 51 et. seq., and the Federal Railroad Safety Act ("FRSA"), 49 U.S.C. § 20109. Plaintiffs Michael Chiaracane ("Chiaracane") and Luis Maldonado ("Maldonado"), employed by defendant Port Authority Trans-Hudson Corporation ("PATH"), as general maintainers, allege that in January 2016 they began using a new cleaning chemical called Tank Brite Plus ("TBP") to clean the outside of train cars. The plaintiffs assert that they were not given any training on the use of TBP or additional safety gear to wear. When the plaintiffs requested respirators for use with TBP, they were not provided immediately. The plaintiffs allege that sometime later, they received respirators with an incorrect filtering cartridge that did not protect them from chemical vapors. The plaintiffs assert that, on March 17, 2016, their coworkers approached the general maintainers' foreman Vincent Lombardi ("Lombardi") complaining they were feeling ill and suffering from headaches and a chemical taste in their mouths from exposure to TBP. Lombardi informed the general maintainers that "they would have to complete double the night work, cleaning two cars instead of customary one." The

plaintiffs assert that, at the end of the shift, at 6:30 a.m., supervisor Robert Kuhfahl (“Kuhfahl”) threatened the jobs of all the general maintainers, stating they would be “out on the street” before TBP would be removed. The plaintiffs continued working with TBP until they sought medical treatment for inhalation injuries. Before the Court is the plaintiffs’ in limine motion. See Fed. R. Evid. 104(a), seeking permission from the Court to present opinion testimony at the trial from Dr. Donald Fox (“Dr. Fox”), a toxicologist, on the issue of causation (Docket Entry No. 120). PATH opposes the plaintiffs’ motion.

### **PLAINTIFFS’ CONTENTIONS**

The plaintiffs assert that “PATH did not monitor the atmosphere while Plaintiffs were using [TBP], therefore such exact measurements [of the atmosphere] do not exist” and “other factors are used to determine dose [of exposure].” Since Dr. Fox “found that no studies of [TBP] have been conducted,” he “relied upon studies of the components of [TBP], which was following proper methodology.” According to the plaintiffs, even without the exact measurements of the atmosphere, Dr. Fox was “able to determine dose [of exposure] for the purposes of rendering a scientifically sound opinion via testimony.” The plaintiffs reported a strong odor of TBP during the entire duration of their eight-hour shift “even when not using the chemical,” and Chiaracane reported that he could smell it through the respirator. The plaintiffs used TBP “for sixty to ninety minutes per shift,” and the “odor was so overwhelming that Maldonado would enter a train and close the doors as an attempt to get fresh air.” Moreover, no ventilation existed in the building “with the bay doors closed during cold or inclement weather and the fans were not working.” The plaintiffs reported holes in their clothes where TBP had splashed, and Maldonado reported skin burns, nose bleeds, shortness of breath, dizziness, warm eyes and throat irritation. Chiaracane experienced nose and throat irritation and dizziness. The plaintiffs’ symptoms

worsened when they were using TBP and improved when they were away from work. The plaintiffs contend that Dr. Fox's "own toxicological research, the medical records, the temporal relation of Plaintiffs' symptoms and their exposure to [TBP], and the testimony of Plaintiffs' exposure constitute a reliable base for his opinions." The plaintiffs maintain that Dr. Fox considered properly the odor threshold in his analysis determining dose of exposure and followed proper toxicological, peer-reviewed methodology. Using the information about TBP's components, Dr. Fox "applied the Bradford Hill Criteria to evaluate the data and reach [his] opinions." According to the plaintiffs, "Bradford Hill has been tested for decades, it has been subjected to peer-review and publication in thousands of articles, and it is a cornerstone of toxicological testing." In support of their motion, the plaintiffs submitted Dr. Fox's curriculum vitae ("CV"), Dr. Fox's "Toxicologist's Expert Report," dated December 28, 2018, Dr. Fox's November 7, 2019 affidavit, excerpts from the plaintiffs' deposition transcripts and a declaration by the plaintiffs' attorney, Patrick J. Finn ("Finn"), with exhibits.

Dr. Fox's CV indicates his educational background as follows: "Postdoctoral, NIEHS Individual Postdoctoral Fellowship: Neurotoxicology and Neurophysiology," "Ph. D. NIEG Predoctoral Fellowship, Environmental Health, Toxicology and Neurobiology," and "B.S., Chemistry." Since 2016, Dr. Fox has been an associate with Robson Forensic, Inc. and he provides "technical investigations, analysis, reports, and testimony toward the resolution of commercial and personal injury litigation involving exposures to drugs, chemicals, toxicants, and other environmental agents and stressors as well as their effect on human health and performance." Dr. Fox's CV indicates that he received honors and awards, held editorial positions, has been a member of various professional organizations and was elected to national positions in various organizations. Dr. Fox has received various grant support, organized and

chaired national and international symposia, held various teaching positions and published numerous peer-reviewed papers and books.

In his December 28, 2018 “Toxicologist’s Expert Report,” Dr. Fox states:

The purpose of my investigation was to perform a causation analysis aimed at determining:

Whether the acute (i.e., daily) exposure to TBP at PATH produced the adverse short-term respiratory and pulmonary symptoms, pathology and functional deficits of Maldonado and Chiaracane.

Whether the five[-]month chronic exposure to TBP at PATH produced the long-term (i.e., persistent) adverse respiratory and pulmonary symptoms, pathology and functional deficits of Maldonado and Chiaracane.

In the section “Materials Available for Review,” Dr. Fox listed various memoranda from and to PATH employees, the plaintiffs’ medical records, the plaintiffs’ Employee Occupational Injury Reports, Maldonado’s responses to PATH’s interrogatories and deposition transcripts of the plaintiffs, Lombardi and Kuhfahl. In the section “Background,” Dr. Fox contends that “[f]rom January to May 2016 PATH did not provide Maldonado and Chiaracane with adequate or proper exposure controls (i.e. good ventilation), respiratory protection, protective clothing for eyes and face, and protective clothing for skin from TBP as outlined in detail in Section 8 of the SDS [safety data sheet],” and Maldonado and Chiaracane were not informed how to dilute TBP properly. From January to May 2016, the plaintiffs complained about TBP’s strong odor, nose bleeds, irritated throats, dry mouth, warm eyes and watery eyes, shortness of breath, coughing and dizziness. On March 17, 2016, Maldonado and Chiaracane were required to clean the same car twice and they received double exposure to TBP on that day. On May 25, 2016, Maldonado and Chiaracane became patients of Dr. Lopa Patel (“Dr. Patel”) who diagnosed them with shortness of breath, tight chests, mixed obstructive and restrictive pulmonary defect, moderate

persistent asthma and reduced pulmonary functions, “consistent with exposure to TBP as stated in the SDS.”

In the section “Background: SDS for TBP,” Dr. Fox recites information from TBP’s SDS, referencing and quoting from its Sections 2, 3, 8 and 11. Dr. Fox states that, “[s]ince PATH did not determine and/or report exposure levels of TBP or any of its constituent ingredients, the actual exposure concentrations are not known.” In the section “Toxicology,” Dr. Fox states, inter alia:

Toxicology involves the study of the pathophysiological effects of chemicals on the human body, tissues and organs as well as on their adverse effects on the health and performance of these tissues and organs and the body. Every toxicology issue involves the analysis of: i) route of exposure, ii) time-dependent duration of exposure, iii) concentration of exposure and iv) mechanism[s] of action of the chemical[s] (Aleksunes and Hayes 2019). In this case, this relates to the external exposure of the skin and eyes to the chemicals in TBP, the time-and concentration-dependent effects following inhalation [i.e., route of exposure] of the chemical constituents in TBP, and the mechanisms of the chemicals on the tissues and organs, such as the skin, lips, eyes, nose, respiratory tract and lungs. Once a chemical is in the body, the toxicologist’s concern invariably and necessarily involves understanding the resulting adverse interaction of the chemical with biological tissues and the subsequent short-term and long-term pathophysiological events. This involves understanding general and specific pharmacokinetic and pharmacodynamic principles as well as the individual chemicals. In general terms, pharmacokinetics describes what the body does to a chemical, whereas pharmacodynamics describes what the chemical does to the body, tissues, and organs (Brunton et al., 2018).

In the section “Composition, Mechanisms and Adverse Pathophysiological Effects of TBP,” Dr. Fox states that “TBP contains 5-15% sulfuric acid, 20-30% phosphoric acid, 5-10% ammonium bifluoride and 1-5% glycol ether EB.” He states that each of TBP’s chemicals “causes concentration-dependent respiratory and pulmonary irritation when inhaled” and the immediate symptoms, “especially for the three acids,” include “burning of the nose and throat, constriction of the airway, difficulty breathing, shortness of breath, bronchial spasms, and chest

pains.” Moreover, “acute exposure to glycol ether EB produces headaches and dizziness.” According to Dr. Fox, “[r]epeated or prolonged inhalation exposure damages the lungs and eventually causes permanent tissue and functional damage,” which “are the respiratory and pulmonary symptoms, pathology and functional deficits seen in Chiaracane and Maldonado.”

Dr. Fox states:

The mechanisms of action of TBP are two-fold. First, the three acids (i.e., sulfuric acid, phosphoric acid and ammonium bifluoride) can directly injure tissue due to their strong acidic (low pH) properties. Second, these acids act as irritants as they can protonate (i.e., add a hydrogen ion) to receptor ligands and other critical biological molecules as well as form numerous types of DNA-, RNA-, protein- and lipid-damaging, damaging free radicals. This effect directly damages membranes, tissues and organs, which then initiates an inflammatory process that disrupts and decreases mucociliary clearance. In the lungs, these chemicals damage the alveolar macrophages. These are the primary phagocytes of the innate (i.e., naturally present) immune system, which clears the lungs of particles that have evaded the mechanical defenses of the nasal passages and mucociliary transport system (Costa and Gordon, 2018; Lehman-McKeeman, 2019; Leikauf, 2019).

In the section “Adverse Pathophysiological Effects of TBP on Maldonado and Chiaracane,” Dr. Fox summarizes the plaintiffs’ symptoms and history of medical treatment by Dr. Patel. In the section “Findings,” Dr. Fox states:

Within the bounds of reasonable scientific and toxicological certainty, and subject to change if additional information becomes available, it is my professional opinion that:

- 1) Chiaracane’s and Maldonado’s daily acute exposure to TBP from January 2016 through May 2016 produced acute respiratory distress, sore throat, dry mouth, watery eyes and nose bleeds, headaches and dizziness. These exposure-related symptoms were evidenced and reported by Chiaracane and Maldonado and are entirely consistent with such information contained in the SDS.
- 2) PATH should have known that the:
  - a) acute symptomology experienced and reported by Chiaracane and Maldonado was directly responsible and entirely consistent with the adverse exposure events associated with daily TBP exposure;
  - b) continued acute daily exposure to TBP over a prolonged period (i.e., in this case five months), as stated in the SDS, would result in long-term adverse chronic respiratory and pulmonary symptoms, pathology and functional deficits; and

- c) lack of adequate and proper protection, as required by their own Safety & Occupational Division and the SDS, would cause these adverse acute and chronic toxicological respiratory and pulmonary effects.
- 3) Chiaracane's and Maldonado's five[-]month chronic exposure to TBP, on a daily basis, directly produced their clinical and objectively documented adverse long-term (i.e., persistent) respiratory and pulmonary, pathology and functional deficits.

In the section "References," Dr. Fox listed various publications.

Dr. Fox states, in his November 7, 2019 affidavit, that he has worked for more than forty years as a toxicologist and professor of "toxicology and pharmacology, biochemistry and vision/neurosciences from 1977 to today." Dr. Fox states:

Throughout those 40 years, the Bradford Hill Criteria, which incorporates a weight of evidence approach, has been a cornerstone standard methodology of toxicology. They were published in a seminal peer-reviewed scientific paper (Hill, 1965) and are widely used by toxicologists. See page 42 of my report reference Aleksunes and Eaton, 2019 for discussion of the methodology for determining causation in toxicology using the Hill criteria (Aleksunes LM, Hayes AN. Principles of Toxicology. In: *Casarett & Doull's Toxicology: The Basic Science of Poisons*. Klaassen CD. McGraw-Hill, New York, pp.25-64, 2019). The section "Causation in Toxicology" on page 42 states the following "In 1965, Sir Austin Bradford Hill set forth a series of considerations intended to infer the likelihood that a particular outcome or disease resulted from a specific "exposure." (Hill, 1965). At the time, these considerations were largely aimed at evaluating relationships using epidemiological and occupational data; however, a similar framework can be applied to evaluate experimental and observation data regarding the toxicity of chemicals."

Dr. Fox states that he used the Bradford Hill Criteria hundreds of times in his work as a toxicologist over the course of his career and he used it as the methodological foundation of his opinion regarding the plaintiffs' exposure to TBP. Dr. Fox explains that, because no epidemiological studies on TBP exist, he researched TBP's components, "reviewing TOXNET reports, Safety Data Sheets or SDS (formerly Material SDS), ACGIH reports, NJ Department of Health and Senior Services Hazardous Substance Fact Sheets, and other studies cited" in the section "References," all of which is "the widely accepted and peer-reviewed methodology

toxicologists use when a mixture has no epidemiological studies to review.” Dr. Fox states that, using the information about TBP’s components, he “applied the Bradford Hill Criteria to evaluate the data and reach” his opinions, which is also widely accepted and peer-reviewed methodology of toxicologists when evaluating components of a mixture with no epidemiological studies. Dr. Fox states that no epidemiological studies exist “that indicate mixing these four components, sulfuric acid, phosphoric acid, ammonium bifluoride, and glycol ether EB, would lessen the hazardous effects of any of the components.” Since actual measurements of the concentration of TBP or its components in the atmosphere while the plaintiffs were using TBP were never recorded by PATH, Dr. Fox also relied on the plaintiffs’ testimony at deposition and medical records as components of the foundation for his opinions. According to Dr. Fox,

Sulfuric acid, one of the four components of [TBP], has an odor threshold which is approximately the same as its NOEL (No Observable Effect Level): the level of exposure at which there is no biologically or statistically significant increase in the frequency or severity of any adverse event. . . . Because sulfuric acid’s NOEL is approximately the same as its odor threshold, Plaintiffs’ testimony that they would smell the chemical indicates that the chemical levels in the atmosphere were above the NOEL, and thus at a level which would produce an adverse toxic effect.

### **PATH’S CONTENTIONS**

PATH contends that Dr. Fox’s supplemental and late affidavit should be stricken and not considered in determining the plaintiffs’ motion. PATH asserts that Dr. Fox’s “report does not mention or provide any methodological analysis of the Hill criteria, odor threshold or its extrapolation, one chemical’s extrapolation to a mixture, or anything with respect to dose [of exposure].” Since Dr. Fox’s report “lacks this toxicological information,” his affidavit should be stricken and not considered. Dr. Fox’s report “was never updated or supplemented and contains no analysis or methodology with respect to any of these newfound methodological issues.”



PATH contends that Dr. Fox's opinion is inadmissible at trial because it "lacks any data or analysis on dose [of exposure], which both his report and the scientific method provide is central to any toxicological analysis." According to PATH, Dr. Fox "failed to his own methodology and the central tenet of toxicology by opining on causation without quantifying Plaintiffs' dose of exposure," and his report "lays no reliable groundwork for this fundamental principle of toxicology because his report includes absolutely nothing on it. His failure to account for this crucial step in his toxicological opinion means that there is 'too great an analytical gap between the data and the opinion proffered.'" Given that "a dose is made up of concentration and duration," "an expert who fails to determine the concentration or duration of exposure cannot perform a dose-response relationship." Since Dr. Fox has no evidence of the plaintiffs' concentration of exposure, his methodology does not rest on sound science and is unreliable. Dr. Fox's report states that every toxicology issue involves the analysis of concentration exposure; yet, he fails to perform any analysis pertaining to this crucial step in any toxicological assessment.

PATH maintains that, even if Dr. Fox's untimely affidavit is admitted in evidence, his opinion is still inadmissible because Dr. Fox avers in his affidavit "that he used Hill criteria" as the methodological foundation of his opinion regarding exposure to TBP but does not "explain or provide his methodology or application of the nine separate Hill criteria or even cite to the Hill criteria." Furthermore, "the Hill criteria is [sic] the province of epidemiologists and any application of these criteria has been heavily scrutinized by the courts." Given that Dr. Fox's report and affidavit contain no information on how he weighed and employed these criteria, his testimony should not be admitted. Dr. Fox's "submissions neither employ epidemiological methodology nor mention it." Dr. Fox's "affidavit mentions that he employed the Hill criteria

but provides no explanation or methodology of how he actually did so.” Moreover, the plaintiffs “cited no caselaw, treatise, or peer reviewed literature that demonstrates that the Hill criteria can be used to extrapolate toxicological information from one chemical to another.” Dr. Fox’s report and affidavit do not provide any information, analysis or methodology “about his use of the Hill criteria to extrapolate one chemical’s properties – sulfuric acid – to another chemical mixture – [TBP].” Stating that the Hill criteria was employed and making a general conclusion is not a methodological basis to extrapolate from one chemical to another. Dr. Fox’s “specious citation to a partial page, which states that ‘a similar framework can be applied to evaluate experimental and observation data regarding the toxicity of chemicals’ does not solve” the methodological gaps, as no “experimental” or “observation” data exist that Dr. Fox created or relied upon with respect to TBP. The only evidence on which Dr. Fox relied consists of the plaintiffs’ self-reporting, which is “not nearly enough to create a ‘statistical association’” between TBP and their alleged illnesses, the first step in the Hill criteria. Once Dr. Fox conceded in his affidavit that “there is no statistical association between a substance and the illnesses alleged”, no basis exists to apply the Hill criteria. PATH asserts that the Hill criteria cannot be applied without knowledge of the dose of exposure. Given that dose-response effect is part of the Hill criteria and Dr. Fox provided neither data nor any reliable groundwork on this crucial element for toxicology, any misapplication of the Hill criteria renders his testimony inadmissible. Moreover, Dr. Fox performed no odor threshold analysis and did not explain the methodology for using it with respect to TBP. Since TBP is “a mixture with several different percentages of several different chemicals,” and it does not have an odor threshold according to its SDS, “smelling it is irrelevant to any exposure analysis.” Thus, Dr. Fox’s reliance on odor threshold to prove exposure is not supported. PATH asserts that, because Dr. Fox “did not do a dose response

curve” for TBP, “any analysis of NOEL is unreliable.” Dr. Fox’s “reliance on MSDS [material safety data sheet] is improper, especially when he has provided no information about what data was used to create the MSDS or any studies pertaining to [TBP] and its effects on humans.” PATH maintains that Dr. Fox’s “attempt to find that Plaintiffs’ injuries are ‘consistent’ with [TBP’s] MSDS is impermissible reverse engineering because he comes to a conclusion without any adequate scientific basis and provides no methodological analysis or basis to do so.” In support of its opposition, PATH submitted a declaration by its attorney with a “sulfuric acid safety data sheet” and TBP’s SDS “cited to in the expert report of [Dr.] Fox.”

### **PLAINTIFFS’ REPLY**

The plaintiffs contend that Dr. Fox “followed an accepted and peer-reviewed scientific method,” namely, the Bradford Hill method, and Dr. Fox’s “first reference cited in [his] report is to the Aleksunes article which is explicit that Bradford Hill is the accepted methodology in toxicology.” According to the plaintiffs, Dr. Fox “properly used evidence and research materials to determine dose” and “found that no studies of [TBP] have been conducted.”

### **LEGAL STANDARD**

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

“It is well settled that expert testimony is unnecessary in cases where jurors ‘are as capable of comprehending the primary facts and of drawing correct conclusions from them as are witnesses possessed of special or peculiar training.’” Wills v. Amerada Hess Corp., 379 F.3d 32, 46 (2d

Cir. 2004) (quoting Salem v. U.S. Lines Co., 370 U.S. 31, 35, 82 S. Ct. 1119, 1122 (1962)).

However, “where an injury has multiple potential etiologies, expert testimony is necessary to establish causation, even in view of plaintiff’s reduced burden to prove causation,” such as under FELA. Id.; see Harrington v. Atlantic Sounding Co., 602 F.3d 113, 138 (2d Cir. 2010) (“This Circuit continues to recognize the distinctive nature of FELA and the Jones Act by applying relaxed standards of negligence and causation to claims brought under those statutes.”).

[T]he Supreme Court has made clear that the district court has a “gatekeeping” function under Rule 702—it is charged with “the task of ensuring that an expert’s testimony both rests on a reliable foundation and is relevant to the task at hand.

In fulfilling this gatekeeping role, the trial court should look to the standards of Rule 401 in analyzing whether proffered expert testimony is relevant, i.e., whether it “ha[s] any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.” Next, the district court must determine “whether the proffered testimony has a sufficiently ‘reliable foundation’ to permit it to be considered.” In this inquiry, the district court should consider the indicia of reliability identified in Rule 702, namely, (1) that the testimony is grounded on sufficient facts or data; (2) that the testimony “is the product of reliable principles and methods”; and (3) that “the witness has applied the principles and methods reliably to the facts of the case.” In short, the district court must “make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.”

Although Rule 702 sets forth specific criteria for the district court’s consideration, the *Daubert* inquiry is fluid and will necessarily vary from case to case. The Supreme Court has identified a number of factors bearing on reliability that district courts may consider, such as (1) whether a theory or technique “can be (and has been) tested”; (2) “whether the theory or technique has been subjected to peer review and publication”; (3) a technique’s “known or potential rate of error,” and “the existence and maintenance of standards controlling the technique’s operation”; and (4) whether a particular technique or theory has gained “general acceptance” in the relevant scientific community. These factors do not constitute, however, a “definitive checklist or test.” Rather, “[t]he inquiry envisioned by Rule 702 is ... a flexible one,” and “the gatekeeping inquiry must be tied to the facts of a particular case.”

Amorgianos v. Nat’l R.R. Passenger Corp., 303 F.3d 256, 265-66 (2d Cir. 2002) (citations omitted).

Courts have considered additional factors in determining whether expert testimony is sufficiently reliable, including: (a) “[w]hether the expert has adequately accounted for obvious alternative explanations”; (b) “[w]hether the expert ‘is being as careful as he would be in his regular professional work outside his paid litigation consulting’”; and (c) “[w]hether the field of expertise claimed by the expert is known to reach reliable results for the type of opinion the expert would give.” Fed. R. Evid. 702 Advisory Committee Notes to 2000 Amendments.

The subject of an expert’s testimony must be “scientific ... knowledge.” The adjective “scientific” implies a grounding in the methods and procedures of science. Similarly, the word “knowledge” connotes more than subjective belief or unsupported speculation. The term “applies to any body of known facts or to any body of ideas inferred from such facts or accepted as truths on good grounds.” . . . [I]n order to qualify as “scientific knowledge,” an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate validation—*i.e.*, “good grounds,” based on what is known. In short, the requirement that an expert’s testimony pertain to “scientific knowledge” establishes a standard of evidentiary reliability.

Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 589-90, 113 S. Ct. 2786, 2795 (1993) (citation omitted).

“[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.” Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146, 118 S. Ct. 512, 519 (1997).

The flexible *Daubert* inquiry gives the district court the discretion needed to ensure that the courtroom door remains closed to junk science while admitting reliable expert testimony that will assist the trier of fact. To warrant admissibility, however, it is critical that an expert’s analysis be reliable at every step. As Chief Judge Becker of the Third Circuit has explained, the *Daubert* “requirement that the expert testify to scientific knowledge—conclusions supported by good grounds for each step in the analysis—means that *any* step that renders the analysis unreliable under the *Daubert* factors renders the expert’s testimony inadmissible.” In deciding whether a step in an expert’s analysis is unreliable, the district court should undertake a rigorous examination of the facts on which the expert relies, the method by which the expert draws an opinion from those facts, and how the expert applies the facts

and methods to the case at hand. A minor flaw in an expert's reasoning or a slight modification of an otherwise reliable method will not render an expert's opinion *per se* inadmissible. "The judge should only exclude the evidence if the flaw is large enough that the expert lacks 'good grounds' for his or her conclusions."

Amorgianos, 303 F.3d at 267 (citations omitted).

"Under *Daubert* and Rule 702 of the Federal Rules of Evidence, the first step in determining the admissibility of expert testimony is determining 'whether the expert is qualified to testify.'"

Cedar Petrochemicals v. Dongbu Hannong Chemical, 769 F. Supp. 2d 269, 282 (S.D.N.Y. 2011) (citation omitted).

Rule 26 of the Federal Rules of Civil Procedure requires that a written report prepared by a witness retained or specially employed to provide expert testimony in the case must contain "a complete statement of all opinions the witness will express and the basis and reasons for them." Fed. R. Civ. P. 26(a)(2)(B)(i). "If a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1). "The purpose of [Rule 37(c)(1)] is to prevent the practice of "sandbagging" an opposing party with new evidence." Ebewo v. Martinez, 309 F. Supp.2d 600, 607 (S.D.N.Y. 2004). However, "preclusion of evidence pursuant to Rule 37(c)(1) is a drastic remedy and should be exercised with discretion and caution." Id.

[T]o the extent that an expert affidavit is within the scope of the initial expert report, it is properly submitted in conjunction with dispositive motions even outside the time frame for expert discovery. Thus, "where an expert's affidavit provides evidentiary details for an opinion expressed in his expert report, those portions of his or her affidavit can be considered."

Cedar Petrochemicals, 769 F. Supp. 2d at 279 (citation omitted).

## APPLICATION OF LEGAL STANDARD

The Court notes that the plaintiffs failed to comply with Rule 26(a)(2)(B) of the Federal Rules of Civil Procedure because Dr. Fox's report does not contain: (a) "a list of all other cases in which, during the previous 4 years, the witness testified as an expert at trial or by deposition," Fed. R. Civ. P. 26(a)(2)(B)(v); and (b) "a statement of the compensation to be paid for the study and testimony in the case," Fed. R. Civ. P. 26(a)(2)(B)(vi). If Dr. Fox did not testify as an expert at trial or by deposition during the previous four years, he did not provide any information stating so.

PATH does not challenge Dr. Fox's qualifications to testify as an expert. Upon review of Dr. Fox's CV, the Court finds that Dr. Fox is qualified to testify as a toxicologist expert concerning causation.

### ***Dr. Fox's December 28, 2018 Toxicologist's Expert Report***

#### **(a) Whether Dr. Fox's Proffered Opinion Testimony Is Relevant**

PATH does not contend that Dr. Fox's proffered opinion on causation is irrelevant. Since causation is an element of the plaintiffs' FELA claims, see 45 U.S.C. § 51, and this case involves TBP, a toxic chemical, jurors may be aided by a toxicologist's testimony interpreting the evidence for the purpose of determining causation. The Court finds that Dr. Fox's proffered opinion testimony is relevant.

#### **(b) Whether Dr. Fox's Proffered Opinion Testimony Is Reliable**

PATH contends that Dr. Fox's proffered opinion is not reliable because it is not based on a reliable scientific method and Dr. Fox failed to follow his own methodology. "In undertaking [the Daubert] flexible inquiry, the district court must focus on the principles and methodology employed by the expert, without regard to the conclusions the expert has reached or the district

court's belief as to the correctness of those conclusions.” Amorgianos, 303 F.3d at 266.

Toxicology is “the science of poisons” and “[a] central tenet of toxicology is that the ‘dose makes the poison’ and that all chemical agents, including water, are harmful if consumed in large quantities.” Mancuso v. Consol. Edison Co. of N.Y., 967 F. Supp. 1437, 1445 (S.D.N.Y. 1997).

Dr. Fox states in his report that “[e]very toxicology issue involves the analysis of: i) route of exposure, ii) time-dependent duration of exposure, iii) concentration of exposure and iv) mechanism[s] of action of the chemical[s].” Other than stating that “[d]uring [a] five[-]month period of daily work exposure to TBP” the plaintiffs “exhibited and complained about” various symptoms, Dr. Fox does not provide any specifics about the: (1) duration of exposure, namely, the daily amount of time during which the plaintiffs were exposed to TBP; and (2) “concentration of exposure,” daily or otherwise. Although the plaintiffs assert in their memorandum of law that the plaintiffs used TBP “for sixty to ninety minutes per shift,” Dr. Fox did not mention or rely on any particular amount of time, including number of minutes, during which the plaintiffs allege they were exposed to TBP on a daily basis. Moreover, “[a]bsent some technical or professional expertise in detecting and quantifying toxic emissions, [the plaintiff’s] testimony was insufficient to establish dosage amount.” Wills v. Amerada Hess Corp., 379 F.3d 32, 49 (2d Cir. 2004).

Dr. Fox states in his report that “the actual exposure concentrations are not known.” Although a lack of data existed on “the actual exposure concentration,” Dr. Fox did not attempt to estimate the concentration of exposure, a necessary element for the analysis of any toxicology issue, according to Dr. Fox. Thus, Dr. Fox failed to apply and follow the methodology that he outlined in his report. Moreover, Dr. Fox did not explain the analytical gaps between the lack of data and the conclusions he made. A determinative mark of the scientific method is drawing



conclusions from and grounding opinions on the existing data. As Dr. Fox did not attempt to (i) determine or estimate the duration and concentration of the plaintiffs' exposure to TBP or (ii) identify and use a scientific methodology toxicologists use to do so in the absence of exact data, he lacked essential information and had no basis upon which to determine whether the duration and concentration of the plaintiffs' exposure to TBP, under the circumstances, could have caused the plaintiffs' alleged harm. When the methodology the expert proffers requires data analysis, such as Dr. Fox's proffered methodology, and the expert makes conclusions based on the lack of data and without any attempt to fill the data gap, such as Dr. Fox did in his report, the Court is not required to admit opinion evidence that is based on "the *ipse dixit* of the expert." Joiner, 522 U.S. at 146, 118 S. Ct. at 519. Dr. Fox's proffered opinion is not derived properly using scientific methodologies and no good grounds support Dr. Fox's conclusions. See Amorgianos, 303 F.3d at 267. The Court finds that Dr. Fox's proffered opinion testimony is not reliable.

***Dr. Fox's November 7, 2019 Affidavit***

(a) Whether Failure To Provide Dr. Fox's Affidavit Timely Was Substantially Justified

Dr. Fox's affidavit, dated November 7, 2019, was submitted after: (i) discovery closed in this action; and (ii) disclosure of his December 28, 2018 report; thus, it is untimely. In their reply, the plaintiffs did not: (a) address PATH's argument that Dr. Fox's supplemental and late affidavit should be stricken and not considered with respect to this motion; and (b) explain the reasons for the untimeliness of Dr. Fox's affidavit. Accordingly, the Court finds that the plaintiffs' failure to disclose Dr. Fox's November 7, 2019 affidavit timely was not substantially justified.

(b) Whether Failure To Provide Dr. Fox's Affidavit Timely Is Harmless

PATH does not contend that it would be prejudiced by admission of Dr. Fox's untimely affidavit and its consideration in determining this motion. PATH is correct that Dr. Fox does not mention "the Bradford Hill Criteria" in his report despite his statement in his affidavit that, throughout "40 years [of his work as a toxicologist and professor of toxicology, pharmacology, biochemistry and vision/neurosciences], the Bradford Hill Criteria, which incorporates a weight of evidence approach, has been a cornerstone standard methodology of toxicology." In the section "Toxicology" of Dr. Fox's report, Dr. Fox states that "[e]very toxicology issue involves the analysis of: i) route of exposure, ii) time-dependent duration of exposure, iii) concentration of exposure and iv) mechanism[s] of action of the chemical[s]," making citation to "Aleksunes and Hayes, 2019." In his affidavit, Dr. Fox states that the Bradford Hill criteria "are widely used by toxicologists," making the following citation: "See page 42 of my report reference Aleksunes and Eaton, 2019 for discussion of the methodology for determining causation in toxicology using the Hill criteria (Aleksunes LM, Hayes AN. Principles of Toxicology. In: *Casarett & Doull's Toxicology: The Basic Science of Poisons*. Klaassen CD. McGraw-Hill, New York, pp. 25-64, 2019)." However, Dr. Fox's report does not make any citation to "Aleksunes and Eaton, 2019" including "page 42" of "Aleksunes and Eaton, 2019," contrary to his statement in his affidavit. Page 42 of "Aleksunes and Eaton, 2019," referenced in Dr. Fox's affidavit, does not mention or reference "Aleksunes and Hayes, 2019," which Dr. Fox cites in his report. Most importantly, page 42 of "Aleksunes and Eaton, 2019" does not, as Dr. Fox states in his affidavit, include a "discussion of the methodology for determining causation in toxicology using the Hill criteria." In "Causation in Toxicology," under the section styled "Assessing Toxicological Responses," on page 42 contained in Exhibit D to Finn's declaration, the following incomplete text appears:

In 1965, Sir Austin Bradford Hill set forth a series of considerations intended to infer the likelihood that a particular outcome or disease resulted from a specific “exposure” (Hill, 1965). At the time, these considerations were largely aimed at evaluating relationships using epidemiological and occupational data; however, a similar framework can be applied to evaluate experimental and observation data regarding the toxicity of chemicals. They are summarized as follows:

1. *Strength of association.* Hill suggested that strong associations between independent and dependent variables could support a causal relationship. For example, a 10 times increase in death rate due to a specific chemical exposure in a defined population could serve as strong evidence in favor of a potential relationship. However, Hill was careful to not readily dismiss

Page 42 was submitted in support of the instant motion as one of the three pages comprising Exhibit D to Finn’s declaration in which Finn states: “Exhibit D is a true and complete copy or excerpts from Aleksunes LM, Hayes AN. Principles of Toxicology. In: *Casarett & Doulls Toxicology: The Basic Science of Poisons*. Klassen CD. McGraw-Hill, New York, pp. 25-64. 2019.” However, certain parts of the text on page 42, under “Causation in Toxicology” appear underlined manually. Finn does not explain who underlined the text or for what purpose. Page 42 contains a statement that a framework “similar” to the framework for assessing causal inference from a specific exposure set forth in 1965 by Sir Austin Bradford Hill “can be applied to evaluate experimental and observation data regarding the toxicity of chemicals.” Page 42 indicates that the relevant “considerations” “are summarized as follows” and contains an incomplete first “consideration,” namely, “*Strength of association.*” Other considerations from “a series of considerations” underlying the “Bradford Hill” causal inference framework are nowhere identified by Dr. Fox in his affidavit, and his report is devoid of any mention of the Bradford Hill “considerations” or “criteria,” including “strength of association.” Having failed to identify a single “consideration” or “criterion” comprising “the Bradford Hill Criteria, which incorporates a weight of evidence approach” and “has been a cornerstone standard methodology of toxicology,” in his affidavit and report, and in the absence of any mention of “the Bradford

Hill Criteria” on page 42 in “Aleksunes and Eaton, 2019,” referenced in Dr. Fox’s affidavit, it appears that Dr. Fox’s affidavit “expound[s] a wholly new and complex approach designed to fill a significant and logical gap” in his report. Cedar Petrochemicals, 769 F. Supp. 2d at 279 (citation omitted). Dr. Fox does not explain in his affidavit or report not only “the Bradford Hill Criteria,” but also the meaning of “a weight of evidence approach,” which he claims “the Bradford Hill Criteria” incorporates. Page 42 does not mention “a weight of evidence approach.” Dr. Fox does not identify in his affidavit any scientific source supporting his proposition that applying “the Bradford Hill Criteria” to “the information about components” of a chemical is “the widely accepted and peer-reviewed methodology of toxicologists when evaluating components of a mixture with no epidemiological studies,” and page 42 does not mention it either.

Moreover, page 42 shows that “a similar framework,” not an identical framework, to the Bradford Hill criteria “can be applied to evaluate experimental and observation data regarding the toxicity of chemicals.” However, Dr. Fox states, in his affidavit, that, in this case, he “used the Bradford Hill Criteria as the methodological foundation of my expert opinions,” not “a similar framework” to the Bradford Hill criteria, which he acknowledges is the standard indicated on page 42 for evaluating “experimental and observation data regarding the toxicity of chemicals.” Not only does Dr. Fox fail to explain and use “a similar framework” to the Bradford Hill criteria, the methodology he announced is used “to evaluate experimental and observation data regarding the toxicity of chemicals,” but he also states that in this case he used “the Bradford Hill Criteria,” the methodology that, according to page 42 on which he relies, is not the methodology to “be applied to evaluate experimental and observation data regarding the toxicity

of chemicals.” Thus, Dr. Fox’s affidavit is internally contradictory and does not support the plaintiffs’ motion.

In his report, Dr. Fox does not mention or analyze anything pertaining to the sulfuric acid “odor threshold” theory that he advances in his affidavit, and TBP’s SDS does not provide information concerning “odor threshold” in general or sulfuric acid “odor threshold” in particular. Dr. Fox, in his affidavit, advances: (a) a new methodology neither identified nor applied in his report, namely “the Bradford Hill Criteria”; and (b) a new theory not mentioned in the report, namely, since the plaintiffs “could smell the chemical,” the sulfuric acid “odor threshold which is approximately the same as its NOEL (No Observable Effect Level)” was “above the NOEL, and thus at a level which would produce an adverse toxic effect.” The Court finds that Dr. Fox’s untimely affidavit, submitted for the first time in support of the plaintiffs’ instant motion, is not harmless because it advances: (a) a new methodology, not mentioned, explained or applied in his report; and (b) a new theory, not mentioned, explained or applied in his report.

Because Dr. Fox’s failure to provide his affidavit timely was not substantially justified and is not harmless, considering it on this motion or admitting the facts contained in it into evidence is not warranted. Alternatively, Dr. Fox’s affidavit does not close the analytical gaps in his report. Although Dr. Fox states, in his affidavit, that he “applied the Bradford Hill Criteria to evaluate the data and reach [his] opinions,” his report does not indicate that he either identified or applied “the Bradford Hill Criteria” to reach his conclusions. Page 42 of “Aleksunes and Eaton, 2019,” referenced by Dr. Fox in his affidavit, indicates “*Strength of association*” as the first consideration of “a similar framework” to the Bradford Hill framework “that can be applied to evaluate experimental and observation data regarding the toxicity of chemicals.” Not only did

Dr. Fox not mention “*Strength of association*” in his report, he also did not attempt to gather any data by performing any experiment(s) or observation(s). Thus, even when considering Dr. Fox’s affidavit on this motion, the Court finds Dr. Fox’s proffered opinion testimony unreliable.

### CONCLUSION

For the foregoing reasons, the plaintiffs’ motion to admit Dr. Fox’s opinion testimony at the trial of this action, Docket Entry No. 120, is denied. The Clerk of Court is directed to close Docket Entry No. 100 as moot.

Dated: New York, New York  
February 25, 2020

SO ORDERED:

  
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KEVIN NATHANIEL FOX  
UNITED STATES MAGISTRATE JUDGE